CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20773

CORRESPONDENCE

BRACCO DIAGNOSTICS

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543-5225

Larry Callan
Director
Regulatory Operations

ORIGINAL

NDN CORRESP
NC.

NDA:20-773

July 17, 1997

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation III
Document Control Room 18B-06
5600 Fishers Lane
Rockville, Maryland 20857

SonoRx®
(simethicone coated cellulose suspension)

Attention: Patricia Y. Love, MD, MBA, Director. Division of Medical Imaging, and Radiopharmaceutical Drug Products (HFD-160)

Dear Dr. Love,

Reference is made to our pending NDA 20-773 for *SonoRx* and the telecommunication with Dr. David Udo on July 14, 1997. Dr. Udo requested a special table to include information on patients with impaired bowel motility/mucosa. and the criteria for diagnosis of bowel impairment, in the clinical report for study 42,440-05 (PK in patients with impaired bowel). Included herewith is a table that provides the demographic characteristics of the patients, the type of bowel impairment, and the criteria for diagnosis.

If you have any questions, or need any additional information, please call me at 609-514-2375.

Thank You

Sincerely,
Madhu Anant
Madhu Anant

Senior Manager, Regulatory Affairs

Tel 609-514-2262 Fax 609-514-2425

BRACCO DIAGNOSTICS

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543-5225

Larry Callan
Director
Regulatory Operations

NDA 20-773

October 8, 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Evaluation III
Document Control Room 18B-06
5600 Fishers Lane
Rockville, MD 20857

Attn: David Place, PhD, Review Chemist
Division of Medical Imaging and Radiopharmaceutical Drug Products (HFD-160)

Dear Dr. Place:

Reference is made to our pending NDA 20-773 SonoRx (simethicone coated cellulose suspension (7.5 mg/mL) submitted September 30, 1996 and to your recent conversation with Larry Callan regarding changes to our proposed labeling.

Please find enclosed four sets of revised color drafts for your review; all labels are true to size. As conveyed to you earlier, we are providing two versions. One version has the Bracco logo placed in the upper left corner (as originally submitted) for the carton label. The logo was reduced in size to address the prominence issue. This is our first choice since this format aligns with the rest of our product labels.

The second version has the Bracco logo placed in the right corner, as suggested and discussed with Larry Callan. Marketing would prefer not to have this version since it will have a different look from all other Bracco product labels.

Please also note that we have now centered the bottle label text. Since the label is going on a 400 mL bottle, it was felt centered text was easier to read than left justified. We hope you agree. We also have submitted two versions of the bottle label; one containing the Bracco logo on the left and one on the right to agree with the carton labels, respectively.

Should you have any questions or require additional information, please call either myself (609-514-2254) or Larry (609-514-2262). We look forward to hearing from you soon.

Sincerely,

Melanie Benson
Sr. Manager, Regulatory Operations

Tel 609-514-2262 Fax 609-514-2425

BRACCO
DIAGNOSTICS

Bracco Diagnostics Inc.
P.O. Box 5225
Princeton, NJ 08543-5225

Larry Callan
Director
Regulatory Operations

NDA: 20-773

October 28, 1998

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug of Drug Evaluation III
Document Control Room 18B-06
5600 Fishers Lane
Rockville, Maryland 20857

Attention: Patricia Y. Love, MD, MBA, Director, Division of Medical Imaging, and Radiopharmaceutical Drug Products (HFD-160)

Dear Dr. Love:

Reference is made to our pending NDA 20-773 for SonoRx® (simethicone coated cellulose suspension), and your faxed correspondence that we received this morning. The correspondence asks that we provide a written agreement to commit to file a labeling supplement containing pediatric dosing recommendations within 12 months.

As requested we commit to file a labeling supplement containing the pediatric dosing recommendations within twelve months. This will be based on oral volume information contained in medical references and literature.

If you require any additional information, please feel free to call me at 609-514-2375.

Sincerely,

Madhu Anant

Madhu Anant
Associate Director
Regulatory Affairs

BRACCO GROUP Tel 609-514-2262 Fax 609-514-2425